Non-Smile Resource			
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Document Title	Document No.: LAB /XXXXX Identification and Control of Nonconformances, Corrective/Preventive Action and Continuous Improvement

Prepared by: Name, Title	

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IDENTIFICATION AND CONTROL OF NONCONFORMANCES, CORRECTIVE ACTION AND CONTINUOUS IMPROVEMENT

General Policy

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The NAME Laboratory recognizes that diligent and effective implementation of this corrective and preventive action policy is very crucial to the success of the quality system.

GENERAL POLICY

Causes of inaccurate/unreliable/poor quality results, late results reporting, wrong specimen submission and other actual and potential quality system non-conformities are continuously investigated and corrective and preventive actions are implemented to prevent their recurrence and to improve the quality system. These actions will be recorded as per the quality system and any changes to the quality system resulting from these actions will be documented.

06.0 PURPOSE

This chapter describes the procedure by which corrective and preventive action is accomplished.

06.1 APPLICATION SCOPE

This procedure applies to all quality system activities at LAB.

06.2 RESPONSIBILITY

Any employee of LAB may propose initiation of the corrective action; but only the Laboratory Director or the Quality Manager can authorize and request for their implementation.

The assignee, which usually is the supervisor of the affected area, is responsible for the completion of the corrective action request form, determination of root cause of the problem, implementation of corrective/preventive action, and recording the results on the Corrective Action Report Form.

The quality manager is responsible for verifying that the corrective/preventive action has effectively eliminated the cause of the nonconformity.

06.3 PROCEDURE

06.3.1 Initiation of Corrective Action

Every laboratory employee is responsible for being aware of any existing or potential nonconformances of the activities of the quality System, in their or any functional section of the laboratory. This, therefore, means that anyone in the laboratory may propose initiation of corrective action by completing the top portion of the Corrective Action Report (CAR) Form.

Nevertheless, only the Laboratory Director or the Quality Manager can authorize and request for their implementation.

Corrective actions may be requested when a condition, which is adverse to quality or which has the potential for process improvement is identified. This includes nonconforming supplies received from a supplier.

Preventive actions may be requested when potential process problems are identified.

Sources of information used to detect, analyze and eliminate existing potential nonconformities may be:

(i) customer complaints
(ii) pre-analytical, analytical and post analytical nonconformances
(iii) noncompliance observed during audits
(iv) nonconforming deliveries from suppliers
(v) identification of nonconformances relating to a process or an operation
(vi) Other occurrences of noncomplying conditions.

The identified nonconformance is registered in the Corrective Action Report (CAR) Form provided by the quality manager. The Quality Manager records all CARs in the Corrective Action Status Log. The Corrective Action Report (CAR) Form is assigned a serial number by the quality manager.

06.3.2 Assessment of Nonconformities

The assessment of the reported quality system nonconformances is carried out by all those involved including the Laboratory Director and the quality manager.

All corrective actions start with an investigation to determine the root cause(s) of the problem. A thorough analysis of all related processes, operations, quality records, and specifications, which may have contributed to the deficiency, is conducted by the responsible function(s). All potential corrective actions are identified and the action(s) most likely to eliminate the problem and to prevent recurrence is selected. The investigation and analysis of the root cause and preventive measures shall be fully documented by the group or individual assigned to the problem. The analysis shall include review of all applicable data to determine the extent and cause of the problem and analysis of trends in processes or performance of work to prevent nonconformances.

This involves a search for the root cause of the nonconformance employing quality control problem solving tools in complicated cases.

All problems are evaluated in terms of potential impact on quality costs, performance, reliability, safety, and customer satisfaction. All problems are classified as either minor or major. Resolutions to all corrective and preventive actions are to a degree appropriate to the magnitude and the risk of the problem. Resolutions are reviewed and approved by the Quality Manager and/or Technical Manager. Where the response is unsatisfactory, the corrective action request is re-issued. The Quality Manager conducts periodic reviews/follow up to determine if the corrective and preventive actions have been implemented and are effective.

Every effort is made to ensure that the client's concerns are assuaged. If lab results are affected, then the customer is notified in writing.

06.3.3 Implementation of Corrective Measures

The corrective measures are implemented via the section supervisors and their subordinates. The responsibility for implementation includes recording the corrective measures executed on the Corrective Action Report (CAR) Form and passing this on to the quality manager. Suitable corrective measures may include:

(i) working out new Quality System Documentation
(ii) servicing, calibration, standardization of test facilities

(iii) decommissioning and/or exchange of test facilities
(iv) training of staff members
(v) improvement of the test methods

06.3.4 Monitoring the effectiveness of Corrective Action

On the basis of the corrective measures, the quality manager supervises the timing, realization and any further measures which may be necessary. The quality manager determines if the corrective measures executed are effective, e.g., by an internal quality audit. The effectiveness is determined by improvement to, and/or elimination of the nonconformity. Positive results are formally concluded and the success documented on the Corrective Action Report Form. If the results are negative, the assessment is reconvened. It is the responsibility of the quality manager to ensure that the results are communicated throughout the laboratory.

06.3.5 Preventive Action

It is the responsibility of the quality manager to analyze the quality system activities, audit results, customer complaints, so as to detect and eliminate potential causes of nonconformities. When preventive actions have been identified, the Laboratory management Team will determine the actions that are required to prevent the potential nonconformances; and these are documented and monitored.

06.3.5 Documentation

All deviations or nonconformances and corrective measures are documented on the Corrective Action Report (CAR) Form and filed in the quality management according to Control of Quality Records Procedure.

06.4 REFERENCES

Not applicable

06.5 CO-APPLICABLE QUALITY MANAGEMENT DOCUMENTS

Corrective Action Report Form
Control of Quality Records Procedure
Corrective Action Status Log

This procedure has been read and understood by the undersigned:

Name of Officer	Signature	Initials	Date

Name of Officer	Signature	Initials	Date